

**Memorandum**

0244 6 JUL 18 2006

Date: JUL 5 2006

From: Consumer Safety Officer, Division of Dietary Supplement Programs, Office of Nutritional Products, Labeling and Dietary Supplements, HFS-810

Subject: 75-Day Premarket Notification of New Dietary Ingredients

To: Dockets Management Branch, HFA-305

Subject of the Notification: **“Angelica gigas Nakai (Korean) Extract”**

Firm: JLM Marketing, Inc.

Date Received by FDA: April 3, 2006

90-Day Date: July 2, 2006

In accordance with the requirements of section 413(a) of the Federal Food, Drug, and Cosmetic Act, the attached 75-day premarket notification and related correspondence for the aforementioned substance should be placed on public display in docket number 95S-0316 as soon possible since it is past the 90-day date. Thank you for your assistance.

\_\_\_\_Victoria Lutwak\_\_\_\_

19955-0316

RPT 344



JUN 14 2006

Mr. Michael G. Jeffers  
700 North Walnut Street  
JML Marketing, Inc.  
Bloomington, Indiana 47408

Dear Mr. Jeffers:

This is to inform you that the notification, dated March 25, 2006, that you submitted pursuant to 21 U.S.C. 350b(a)(2)(section 413(a)(2) of the Federal Food, Drug, and Cosmetic Act (the Act)) was filed by the Food and Drug Administration (FDA) on April 3, 2006. Additional information was received on April 13. Your notification concerned the substance that you called "Angelica gigas Nakai (Korean) Extract" that you identify as a new dietary ingredient that you intend to market in a dietary supplement product called "Decursinol™". According to your notification, "Angelica gigas Nakai (Korean) Extract" is derived from the roots of *Angelica gigas Nakai*.

Under 21 U.S.C. 350b(a), the manufacturer or distributor of a dietary supplement containing a new dietary ingredient that has not been present in the food supply as an article used for food in a form in which the food has not been chemically altered must submit to FDA, at least 75 days before the dietary ingredient is introduced or delivered for introduction into interstate commerce, information that is the basis on which the manufacturer or distributor has concluded that a dietary supplement containing such new dietary ingredient will reasonably be expected to be safe. FDA reviews this information to determine whether it provides an adequate basis for such a conclusion. Under 21 U.S.C. 350b (a) (2), there must be a history of use or other evidence of safety establishing that the new dietary ingredient, when used under the conditions recommended or suggested in the labeling of the dietary supplement, will reasonably be expected to be safe. If this requirement is not met, the dietary supplement is considered to be adulterated under 21 U.S.C. 342(f) (1) (B) because there is inadequate information to provide reasonable assurance that the new dietary ingredient does not present a significant or unreasonable risk of illness or injury.

Your notification does not comply with the requirements of 21 CFR 190.6 and is incomplete. Your notification does not provide information concerning the conditions of use of the supplement that will contain your ingredient as required by 21 CFR 190.6 (b)(3)(ii).

In addition, based on the information in your notification, FDA was unable to determine the identity of "Angelica gigas Nakai (Korean) Extract". Your notification contains no

information that describes how the roots are processed or extracted during the preparation of your ingredient.

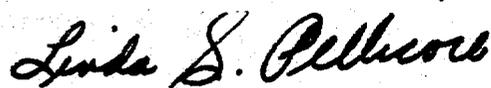
Furthermore, the serving levels and form of the product you intend to market are unclear to FDA. For example, your notification describes a product called "Joinwell" that is said to be marketed by Scigenic Co., LTD in South Korea in capsule form. It is unclear to FDA how "Joinwell" is related to "Decursinol™", whether the quantities given as the serving levels for "Joinwell" refer to the levels of "Angelica gigas Nakai (Korean) Extract" in that product, whether the conditions of use for "Decursinol™" will be the same as those for "Joinwell". It is also unclear to FDA whether "Decursinol™" will be marketed in capsule form, as is "Joinwell" or in some other form.

For the reasons discussed above, the information in your submission does not provide an adequate basis to conclude that "Angelica gigas Nakai (Korean) Extract", when used under the conditions recommended or suggested in the labeling of your product, will reasonably be expected to be safe. Therefore, your product may be adulterated under 21 U.S.C. 342(f)(1)(B) as a dietary supplement that contains a new dietary ingredient for which there is inadequate information to provide reasonable assurance that such ingredient does not present a significant or unreasonable risk of illness or injury. Introduction of such a product into interstate commerce is prohibited under 21 U.S.C. 331(a) and (v).

Your notification will be kept confidential for 90 days after the filing date of April 3, 2006. After the 90-day date, the notification will be placed on public display at FDA's Docket Management Branch in docket number 95S-0316. Prior to that date, you may wish to identify in writing specifically what information you believe is proprietary, trade secret or otherwise confidential for FDA's consideration.

If you have any questions concerning this matter please contact Victoria Lutwak at (301) 436-1775.

Sincerely yours,



Linda S. Pellicore, Ph.D.  
Supervisory Team Leader, Senior Toxicologist  
Division of Dietary Supplement Programs  
Office of Nutritional Products, Labeling  
and Dietary Supplements  
Center for Food Safety and Applied Nutrition

March 25, 2006



## DSHEA SUBMISSION/ NOTIFICATION

**Sender:** Michael G. Jeffers

**Company:** JLM Marketing, Inc.  
700 North Walnut Street  
Bloomington, IN 47408  
Phn#: (h) 812-336-6385  
(o) 812-330-1526

2006-2860

**Name of the New Dietary Ingredient:**

*Angelica gigas Nakai (Korean) Extract*

**Description of New Dietary Ingredient:**

- a) Level of the Ingredient is 100% since it is an extract. The main component of the extract specification is called Decursin, and the secondary, minor component is called Decursinol. Specification Enclosed (as Exhibit DS).
- b) Stated conditions of use range from reduction of joint inflammation, to memory support. The end use company putting the extract into finished form will define the actual use in their marketing efforts. We are marketing as an ingredient, with human clinical data to define potential use areas as Enclosed (note Exhibit HCS).
- c) Historical Data in Angelica gigas Nakai (Korean) Extract is historically present within the Korean culture dating back to the 1600's. the evaluation process of the human clinicals was to validate the popular idea of potential uses of the Angelica gigas Nakai root extract for health benefits.

d) Safety of the product has been tested within animal studies and human clinical evaluations, double blind. The Studies of course are enclosed. We have sent a summary of the human studies to several companies for evaluation to get their opinion on potential application ideas. Enclosed is the Power Point Summary which also includes several points and show several graphs outlining toxicity, safety, and the non-addictive qualities of the Angelica gigas Nakai (Korean) extract (**note exhibit PP**).

e) Summary of Key Points of Human Studies (Enclosed within exhibit PP)

- 1) Toxicity-The patients showed a remarkable response to the Angelica gigas Nakai as compared to the placebo group
- 2) Non-Addictive as compared to Cox 2 inhibitors (opiate)
- 3) Non-Gastro effects as compared to Cox 1 inhibitors
- 4) All negative results on Acute Tox, Genetic Tox, and Subacute Tox
- 5) VAS scoring quite a bit higher compared to placebo group

f) The inventor of the Angelica gigas Nakai (Korean) Extract is the following:

Scigenic Co., LTD  
#701 aT Center, 232, Yangjae-Dong,  
Seocho-Gu  
Seoul 137-787  
Korea

Signed by:

Michael G. Jeffers:

March 25, 2006

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APR 13 2006

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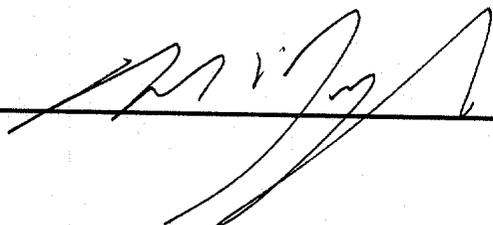
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Seocho-Gu  
Seoul 137-787  
Korea

Signed by:

Michael G. Jeffers:



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March 25, 2006

## **DSHEA SUBMISSION/ Additional Info ENCLOSED**

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**Company:** JLM Marketing, Inc.  
700 North Walnut Street  
Bloomington, IND 47408  
Phn#: (h) 812-336-6385  
(o) 812-330-1526

**To:** Division of Standards and Labeling Regulations  
Office of Nutritional Products, Labeling, and Dietary  
Supplements, Center for Safety and Applied Nutrition  
Food and Drug Administration

**RE:** New Dietary Ingredient filing for Angelica gigas Nakai  
(Korean) Extract. Additional categories noted in A-E as  
requested, or relative to the evaluation of this potential Dietary  
Supplement.

**A) Stated Conditions of Use, Angelica gigas Nakai  
(Korean) Extract**

Dosage Rates from Human Clinical Studies:

- 1) To achieve 98% effectiveness suggested dosage rates per the  
"inventor" the recipient would take 300 mgs twice per day
- 2) Response time to intake is projected at 50-90 minutes per the inventor,  
Scigenic Co., LTD.
- 3) Human clinical evaluations were conducted on a double blind study of  
80 people and dosage rates for the human tests were conducted with  
500 mgs of the Agelica gigas Nakai Extract twice per day.
- 4) Commercial Forms in South Korea (Joinwell) provide dosage rates  
As 240mg. 300mg, and 500mg.

**B) Genus Name, species**

- 1) Genus Name; Angelica
- 2) Author; Nakai
- 3) Family; Umbelliferae
- 4) Synonyms: Angelica cryptotaeniifolia-Kitag
- 5) Range; East Asia
- 6) GWB78; this is the code # used during research of the Angelica gigas Nakai Extract. The commercial name will be Decursinol™

APR 13 2006

**C) Signed copies of the initial filing from 3/25/06 ;  
ENCLOSED- 3 pages**

**D) COMMERCIAL USES OF Angelica gigas Nakai  
(Korean) Extract**

- 1) Product has been sold commercially in South Korea for the past 24 months. The Commercial form is in a 2-piece capsule and is called Joinwell.
- 2) Joinwell in finished form includes excipients such as flow agents, Dicalcium Phosphate, and Glucosamine Sulfate, along with the Angelica gigas Nakai Extract.
- 3) Joinwell is sold in South Korea on the Internet and in stores, by the inventor and manufacturer, Scigenic Co., LTD.  
([www.scigenic.com](http://www.scigenic.com)). Each bottle includes 60 capsules.

**E) STABILITY DATA**

- 1) Enclosed as Exhibit SD and defining the stability of the Angelica gigas Nakai (Korean) Extract or the Res. Code # assigned which is GWB78, or the Commercial designation called Decursinol™.

Signed: \_\_\_\_\_

Michael G. Jeffers

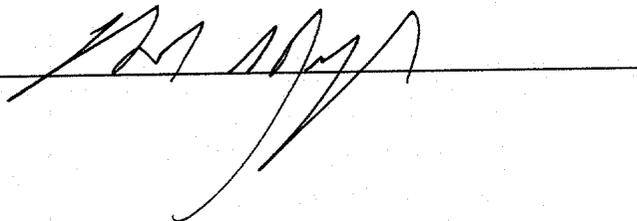


EXHIBIT SD

3 PAGES TOTAL

REDACTED IN ITS

ENTIRETY

CONTAINS

TRADE SECRET

CONFIDENTIAL

COMMERICAL

INFORMATION

EXHIBIT DS

1 PAGE TOTAL

REDACTED IN ITS

ENTIRETY

CONTAINS

TRADE SECRET

CONFIDENTIAL

COMMERICAL

INFORMATION

EXHIBIT HCS  
15 PAGES TOTAL

REDACTED IN ITS  
ENTIRETY  
CONTAINS  
TRADE SECRET  
CONFIDENTIAL  
COMMERICAL  
INFORMATION

**EXHIBIT PP**

**8 PAGES TOTAL**

**REDACTED IN ITS**

**ENTIRETY**

**CONTAINS**

**TRADE SECRET**

**CONFIDENTIAL**

**COMMERICAL**

**INFORMATION**